

## INFANT BOTULISM TREATMENT AND PREVENTION PROGRAM

The mission of the Infant Botulism Treatment & Prevention Program (IBTPP) is to provide and improve the treatment of infant botulism, and to prevent infant botulism and related diseases. The IBTPP was established in May 1997 when its multi-year clinical trial of the Orphan Drug Human Botulism Immune Globulin (BIG) demonstrated the safety and efficacy of BIG as the first specific treatment for infant botulism.

The IBTPP is statutorily established as a fee-supported, special fund activity that produces and distributes BIG statewide and nationwide; provides diagnostic and consultative medical services for infant botulism; investigates all cases of infant botulism in California; develops and implements prevention and control measures for infant botulism and related illnesses (e.g., SIDS and crib death); and carries out applied research into improving the treatment of infant botulism and related illnesses.

## What is Infant Botulism?

Infant botulism is an uncommon disease caused by the spores of *Clostridium botulinum*, a bacterium naturally found in soil. Infant botulism results from swallowing the spores of the botulinum bacteria, which then grow in the large intestine and release botulinum toxin that is absorbed into the circulation. The toxin causes muscle paralysis when it damages the nerve endings and disrupts signaling between the nerves and muscles. Muscle control returns only after the slow-growing nerve endings regenerate.

The clinical symptoms of infant botulism are constipation, weakness, loss of muscle tone, lethargy, listlessness, poor feeding, weak cry, difficulty nursing, expressionless face, droopy eyelids, inability to swallow, loss of head control, and, infrequently, sudden cessation of breathing (respiratory arrest). Before the development of BIG, the only treatment available was meticulous supportive care, such as feeding and breathing for the paralyzed infant.

Each year, between one-third and one-half of the 70-80 cases reported nationwide occur in California. Approximately 94 percent of cases occur in infants 1 to 6 months of age. Infants with the disease who are not treated with BIG may be hospitalized for weeks to months, and the cost of their hospital care may exceed \$100,000. During its clinical trial, BIG reduced average hospital stay by approximately three weeks and average hospital costs by approximately \$70,000 per case.

## **Information Resources**

For more information about infant botulism or about obtaining BIG, please contact the IBTPP at (510) 540-2646, or visit www.dhs.ca.gov/ps/dcdc/html/ibtindex.htm.